

Remarks:

1. Objections and Rejections.

Applicants acknowledge with appreciation that the Examiner has not renewed his previous indefiniteness and anticipation rejections and that the Office Action now indicates that claims 9-11, 16-18, and 22-24 contain allowable subject matter and would be allowable if rewritten in independent form to include the limitations of their base claims and any intervening claims. Nevertheless, the Office Action objects to claims 42 and 43 as allegedly including informalities and rejects claims 1-3, 12-15, 19-21, and 42 and 43 under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Patent No. 5,766,240 to Johnson. Applicants respectfully traverse.

2. Anticipation Rejections.

Claims 1-3, 12-15, 19-21, and 42 and 43 stand rejected as allegedly anticipated by Johnson. “A claim is anticipated if and only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. . . . [Moreover, ‘t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” MPEP 2131 (emphasis added; citations omitted). Applicants respectfully disagree with these rejections.

Referring to Johnson’s **Figs. 7-9**, the Office Action contends that

Johnson discloses an apparatus comprising: a first cylinder (120) having first and second ends, the second end having an adjacent exterior lip (120.1) for securing to an interior groove (130.6) on a second cylinder (130). Johnson also discloses an apparatus comprising: a first cylinder having first and second ends, the second ends, the second end having an adjacent exterior annular groove for securing to an interior lip on a second cylinder (Figs. 7 and 8). The first cylinder has a fabric annular cuff surrounding the exterior surface adjacent to the first end. The first and second securing means of Johnson are **capable** of “fixing sutures therebetween”, and therefore meet the structural limitations.

Office Action, Page 3, Lines 16-24 (bolding in the original). Applicants respectfully disagree.

The Office Action has failed to demonstrate that Johnson anticipates Applicants’ claimed invention for at least three reasons. **First**, Johnson does not disclose (or suggest) and the Office Action does not contend that Johnson discloses the fixing of sutures between “first cylinder (120)” and “second cylinder (130).” Thus, the Office Action has failed to demonstrate

“that each and every element as set forth in the claim is found, either expressly or inherently described, in [Johnson]. MPEP 2131 (emphasis added). As noted above, the Office Action does not allege that Johnson “expressly” discloses that Johnson’s “cylinders” are “adapted to secure fixing sutures therebetween,” but Applicants maintain that this feature of the claimed invention also is not “inherently” described in Johnson.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. . . . “To establish inherency, the extrinsic evidence ‘must make the clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’”

MPEP 2112(IV) (emphasis in original; citations omitted). Applicants maintain that the Office Action has not provide evidence to show that Johnson “necessarily” is “adapted to secure fixing sutures therebetween,” and that this adaptation would be “recognized by persons of ordinary skill.” Therefore, each and every element of Applicants’ claimed invention is neither expressly or inherently disclosed by Johnson.

Second, the Office Action appears to equate the term “adapted to” with “capable of.” This is incorrect. The term “adapted” is defined as “suited by nature, character, or design to a particular use, purpose, or situation - used with *to* or *for*.” Webster’s Third New International Dictionary, 24 (1971) (emphasis added; italics in the original). Even if the Office Action’s assertion were correct that Johnson’s components were “capable of ‘fixing sutures therebetween,’” this would not mean that Johnson is “adapted to secure fixing sutures therebetween.

Third, although the Office Action alleges that Johnson’s apparatus is “**capable**” of “fixing sutures therebetween” without further modification, Applicants maintain that the Office Action has not shown that persons skilled in the art would interpret Johnson is in that manner. First, Johnson specifically states that

[i]n the implantation of such heart valves, the surgeons are instructed to carefully direct curved suture needles through the valvar rim and the periphery of the suturing ring fabric 14.1 so that the sutures enter and exit the fabric 14.1 at a

distance away from the interface with the valve body 12. Moreover, the suture needle should be passed through the fabric 14.1 in a manner to avoid penetrating and possibly severing the cord(s) 16 and the seam 14.3. Referring again to FIG. 2, surgeons are instructed to follow a curved suture path in the direction of arrow A--A to avoid penetrating these structures and so that the resulting acceptable suture knot and tails S.sub.A of the tied off suture are out of interference with valve structure. If these instructions are not carefully followed unacceptable suture knots and tails S.sub.U (examples shown in FIGS. 1 and 2) may be tied off so close to the interface that they may be flushed into the valve orifice and interfere with closure or opening of the valve mechanism.

Johnson, Column 5, Lines 12-28 (emphasis added). Johnson goes on to explain that it is an object of his invention to achieve sufficient separation between the suture placement and the valve annulus. *Id.* at Lines 60-64. Second, in all embodiments of Johnson's invention, "[a]ll of the valves are characterized by having an annular valve body carrying a circumferential, rotatable suturing ring permitting rotation of the valve after the suturing ring is sutured to the valvar rim remaining after removal of a patient's diseased heart valve." Johnson, Column 8, Lines 5-9 (emphasis added). If the valve body, such as valve body 120, may rotate with respect to the suturing ring, such as suturing ring 130, even if, contrary to surgical practice, a suture was placed between the valve body and the suture ring, it could not be fixed therebetween.

In view of the foregoing remarks, Applicants maintain that the Office Action has failed to demonstrate that Johnson expressly or inherently discloses each and every element of the claimed invention. Thus, the Office Action has failed to demonstrate that claims 1-3, 12-15, 19-21, and 42 and 43 are anticipated by Johnson. Therefore, Applicants respectfully request that the Examiner withdraw the anticipation rejections to these claims.

Conclusion:

Applicants respectfully submit that this application, as amended, is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that a further interview with Applicants' representatives, either in person or by telephone, would expedite

prosecution of this application, we would welcome such an opportunity.

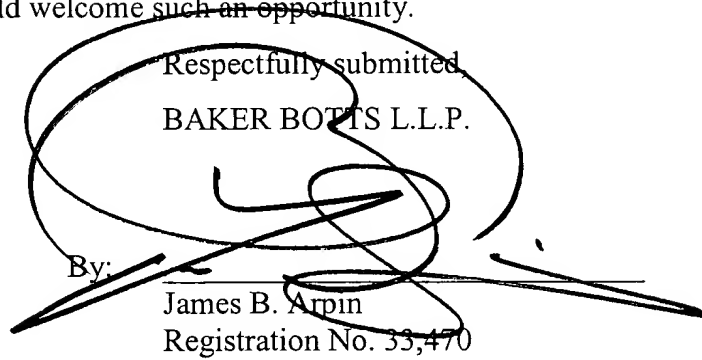
Respectfully submitted,
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Enclosures

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